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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,655	02/04/2005	Alan P. Escher	14102-1US	3703

23676 7590 12/12/2007

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,655	ESCHER ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response received on 9/27/07 has been entered. Claims 3-4, 11, and 19-24 are canceled. Claims 1-2, 5-10, and 12-18 are currently pending and under examination in the instant application. An action the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/6/07 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy attached to this action. Please note that the references listed in the International Search Report, reference 6, have been submitted as references 1-5.

Claim Rejections - 35 USC § 112

The rejection of claims 1-2 and 5-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of claim 11 and the amendments to claims 1-2, 5-10, and 12-18, which are now limited to where the construct encodes secreted glutamic acid decarboxylase.

The rejection of claims 1-2, and 5-18 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn over cancelled claim 11 and maintained in part over amended claims 1-2, 5-10, and 12-18. Applicant's amendments and comments have been fully considered but have not been found persuasive in overcoming the rejection for reasons of record as discussed in detail below.

The applicant states that the claims have been amended as outlined in the Office Action, and that therefore the pending claims are patentable. In response, while the claims have been amended to limit the autoantigen to secreted glutamic acid decarboxylase, and the autoimmune disease to type I diabetes, the claims as amended do not in fact correspond to the scope of enablement identified in the previous office action. The previous office action stated that that the specification, while being enabling for 1) a method of inhibiting the development of diabetes type 1 in a patient comprising administering by intramuscular injection a plasmid DNA which comprises a polynucleotide sequence encoding soluble GAD 55 (sGAD 55) and a polynucleotide sequence encoding Bax operatively linked to a CMV promoter, 2) a plasmid DNA for inhibiting the development of diabetes type 1 which comprises a polynucleotide sequence encoding soluble GAD 55 (sGAD 55) and a polynucleotide sequence encoding Bax operatively linked to a CMV promoter, does not reasonably provide enablement for methods for preventing, delaying the onset of or treating any pre-existing autoimmune disease in a patient by administering by any route of administration any polynucleotide construct encoding Bax and one or more autoantigens for the autoimmune disease. The claims as amended, however, including the composition claims, continue to recite "preventing, delaying the onset of or treating" type I

diabetes, and further continue to read broadly on any polynucleotide construct., and any route of administration of the construct. Thus, the claims as amended have not in fact been amended as outlined in the previous office action. While the amended claims do overcome issues of non-enablement raised in regards to the genus of autoimmune diseases and autoantigens, the amendments to the claims do not address the issues of non-enablement raised in regards to the use of any polynucleotide construct, any route of construct administration, or the prevention of or treatment of pre-existing autoimmune disease, including diabetes, using genetic vaccination, see pages 7-12. Further applicant's response does not address these issues or provide any arguments traversing these grounds of rejection. Therefore, applicant's amendments and comments are not persuasive in overcoming the rejection of record.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633